



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: Environmental risk assessment for the FIFRA Section 3 new use registration of *Paecilomyces fumosoroseus* Apopka Strain 97 (EPA Reg. No. 70051-19)

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I. Environmental Risk Assessment

A. Introduction

Certis U.S.A, L.L.C. (hereafter "Certis") has submitted an application to allow for additional uses of *Paecilomyces fumosoroseus* Apopka Strain 97 on all outdoor-grown food, non-food, and seed crops. *Paecilomyces fumosoroseus* Apopka Strain 97 is the active ingredient (a.i.) in the end-use product (EP) PFR-97 20% WDG. This EP is 20% a.i. and contains 1×10^9 cfu/g of *Paecilomyces fumosoroseus* Apopka Strain 97.

Paecilomyces fumosoroseus is an entomopathogen that is known to have a relatively wide host range. It was recently reclassified into *Isaria fumosorosea* (Zimmermann 2008), but to be consistent with the a.i. name, it will be referred to with its previously recognized name throughout this assessment. According to Zimmermann (2008) *Isaria fumosorosea* (*Paecilomyces fumosoroseus*) actually forms a species complex, which may account for some differences in host range and environmental conditions that it has been found to tolerate. It is widely distributed, has been isolated from many species of insects, particularly Lepidoptera, and has been collected from air, water, plants, other fungi, and often from soil. It is one of the most

common entomopathogens known to affect nymphs and adults of *Bemisia* spp. of whiteflies, and has caused epizootics in this species in the U.S. and other countries (Zimmermann 2008).

This EP containing *Paecilomyces fumosoroseus* Apopka Strain 97 was previously registered for use in greenhouse and interiorscapes only. At that time, several data requirements were waived due to the lack of exposure to nontarget organisms. The proposed expanded uses pose an increased potential for exposure to nontarget organisms, and require submission of additional data and a new environmental risk assessment. This memorandum contains BPPD's ecological risk assessment for the proposed new use registration of *Paecilomyces fumosoroseus* Apopka Strain 97.

B. Summary of Nontarget Effects Data

Table 1 provides the status of the data requirements for the active ingredient *Paecilomyces fumosoroseus* Apopka Strain 97 for ecological risk assessment of the new uses. Guideline studies and data waiver rationale were submitted to satisfy data requirements for nontarget organisms as published in 40 CFR § 158.2150. The avian oral toxicity/pathogenicity data requirement was satisfied when this active ingredient was initially registered for greenhouse use, and additional data were not required for the new proposed uses. Information from the additional studies and data waiver rationale is included in the discussion of risk below (see section C), and Data Evaluation Records (DERs) are attached. The information provided is sufficient to satisfy the Tier I nontarget organism data requirements and for nontarget organism risk assessment for the new uses. BPPD (1996) stated that environmental fate data would be required for this a.i. if adverse effects are observed from Tier I studies. Additional testing at higher tiers is not being required at this time, but may be needed for more refined risk assessments (e.g., for endangered species) in the future.

Table 1. Summary of data submitted to comply with nontarget organism data requirements published in 40 CFR § 158.2150 for support of the registration of *Paecilomyces fumosoroseus* Apopka strain 97.

Data Requirement	OPPTS Guideline No.	Results Summary and Classification	MRID No.
Avian oral toxicity/pathogenicity	885.4050	A study (supplemental) indicated that <i>P. fumosoroseus</i> Apopka Strain 97 is not toxic or pathogenic to birds. <i>P. fumosoroseus</i> Apopka Strain 97 does not grow at avian body temperatures and is not expected to pose a hazard to birds	43534803
Avian inhalation toxicity/pathogenicity	885.4100	Not required. <i>P. fumosoroseus</i> is not pathogenic to birds.	N/A
Wild mammal toxicity/pathogenicity	885.4150	Tests required by 40 CFR § 158.2140 are adequate/ appropriate for assessment of hazards to wild mammals. <i>P. fumosoroseus</i> Apopka Strain 97 was not toxic or pathogenic to albino rats at 1.7×10^6 cfu/animal. Scientific rationale also support the conclusion that adverse effects to wild mammals are not expected. Classification: Acceptable	47939507

Data Requirement	OPPTS Guideline No.	Results Summary and Classification	MRID No.
<ul style="list-style-type: none"> Freshwater fish toxicity/pathogenicity Freshwater invertebrate toxicity/pathogenicity 	885.4200 885.4240	Data waiver rationale provides sufficient information to determine that toxicity/pathogenicity to freshwater fish and invertebrates is not expected as a result of all applications except for aerial applications. Classification: Supplemental for aerial applications, Acceptable for all other applications	47939506
Estuarine/marine fish and invertebrate testing	885.4280	Not required. <i>P. fumosoroseus</i> is not to be applied directly to water and is not expected to reach estuarine or marine environments in significant quantities. <i>P. fumosoroseus</i> was also shown to be nonpathogenic to two species of estuarine invertebrates.	N/A
Nontarget plant testing	885.4300	Scientific rationale was sufficient to conclude that no adverse effects are expected to nontarget plants. <i>Paecilomyces fumosoroseus</i> Apopka strain 97 is not related to any known plant pathogen and testing is not required. Classification: Acceptable	47939504
Nontarget insect testing	885.4340	Initial scientific rationale (MRID 47939505) was unacceptable . Additional rationale provides sufficient information to conclude that <i>Paecilomyces fumosoroseus</i> Apopka strain 97 will be pathogenic to some nontarget species of insects Classification: Acceptable	47939505 48357703
Honey bee testing	885.4380	A honey bee study showed that <i>Paecilomyces fumosoroseus</i> Apopka strain 97 is not toxic to honey bees. Classification: Supplemental Additional rationale show that pathogenicity may not be likely, but a conclusion cannot be made without uncertainty. Classification: Acceptable	47939509 48357704

C. Ecological Exposure and Risk Characterization

1. Terrestrial Animals and Plants

The EP is a water dispersable granule that is proposed for application to all outdoor food, non-food, and seed crops. The proposed new applications are to be made to foliar surfaces by using hand-held, ground, or aerial spray application equipment, or to soil by drench or spray, chemigation (including drip, trickle, and overhead sprinkler), or injection. Applications are to be made at 1- 2 lbs/acre, and can be repeated every 3-10 days.

Data on natural concentrations of *Paecilomyces fumosoroseus* and persistence of this strain in the environment are not available. Many factors influence persistence, including availability of hosts and environmental conditions, and population growth of *Paecilomyces fumosoroseus* Apopka strain 97 following treatment cannot be predicted. BPPD expects, however, that the applied fungus may grow to some degree, but the population levels will be reduced as host insects die off. Also, since retreatment is needed every 3-10 days, the a.i. is not expected to persist at effective levels in the environment for very long, except with retreatment or in areas where host insects may sustain its population. Tier II environmental expression studies would resolve uncertainties about the environmental fate of *Paecilomyces fumosoroseus* Apopka Strain 97.

Most soil directed applications (except some sprays) and chemigation are primarily expected to confine nontarget exposure to the area intended for treatment, though exposure may occur on the treated area via contact with soil and foliar surfaces. Soil applications that require incorporation or injection into the soil will reduce exposure to many nontarget organisms, except soil-dwelling insects and other sensitive arthropods. Some movement via runoff may occur with heavy rain, but since the proposed applications can be made to foliar surfaces via aerial and ground sprays, drift is expected to account for the majority of offsite movement. Aerial sprays were expected to deposit more of the applied *Paecilomyces fumosoroseus* Apopka Strain 97 offsite, and also further away from the treated area. For example, aerial applications are expected to deposit 22.3% and 17.1% of the applied amount at 25 and 50 feet away, respectively, whereas ground sprays (using a 50 inch boom height) are expected to deposit 10.4% and 5.0% at those same distances, respectively. These percentages were determined using the AgDRIFT® spray drift analysis tool, assuming fine to medium droplet size for aerial applications and very fine to fine droplet size for ground applications. BPPD does not have data (e.g., from efficacy studies) to determine whether these amounts would result in risk to sensitive arthropods; however, that information would be useful in refining determination of nontarget risks and the extent to which effects may occur.

Birds and Mammals

Birds and mammals may be exposed to *Paecilomyces fumosoroseus* Apopka Strain 97 through consumption of treated insects and other food items contacted at application. Any birds and mammals present at application could be exposed via inhalation, as well as consumption of drinking water nearby or on treated fields. Studies show that adverse effects are not expected in birds as a result of exposure to *Paecilomyces fumosoroseus* Apopka Strain 97, and that this fungus does not grow at avian body temperatures. Studies with laboratory rats indicate that *Paecilomyces fumosoroseus* Apopka Strain 97 is not toxic or pathogenic to mammals. Concerns were also raised in previous assessments about beauverolides (mycotoxins) that may be produced by *Paecilomyces fumosoroseus* Apopka Strain 97. To support these proposed new uses, the registrant submitted information to show that beauverolides were present in negligible concentration in liquid fermentation. BPPD concluded that this was not of concern, but required testing for beauverolides in production batches. As long as beauverolides are not present in significant quantities, there will be no concern for potential toxicity to nontarget organisms. This information is sufficient to show that adverse effects to birds and mammals are not expected to

result from exposure following application of *Paecilomyces fumosoroseus* Apopka Strain 97 for the proposed new uses.

Nontarget Insects

Nontarget insects and other sensitive arthropods are expected to be exposed to *Paecilomyces fumosoroseus* Apopka strain 97 on the treated field, and may be exposed in areas to which treatment may drift. Insects may be directly sprayed or they may contact *Paecilomyces fumosoroseus* Apopka Strain 97 that is present on treated foliar and soil surfaces. Some exposure to soil dwelling insects may occur in treated areas below the soil surface. Since many different crops may be treated with a variety of application types, insects or other sensitive arthropods that occupy many different ecological niches are expected to receive exposure as a result of the proposed labeled uses.

Certis presented rationale as well as the results of several studies of various strains of *P. fumosoroseus* with nontarget insects to justify that nontarget effects are not to be expected. Current and former registrants of *Paecilomyces fumosoroseus* Apopka strain 97 performed several studies with nontarget insects, but these were not suitable for review. Other studies performed on *Paecilomyces fumosoroseus* Apopka strain 97 on nontarget insects were described but not provided for review by BPPD. Copies of studies from the literature were included, however, and do provide some information with which to determine the potential for adverse effects on insects and the risk to nontarget insects resulting from the proposed new uses.

Based on the information presented, as well as some other information discussed below, it is evident that *P. fumosoroseus* Apopka Strain 97 has the potential to affect some, but possibly not all, species of insects and other terrestrial arthropods. It is apparent that the host range of *P. fumosoroseus* may not be as extensive as other entomopathogenic fungi, such as *Beauveria bassiana* or *Metarhizium anisopliae*; however, *P. fumosoroseus* does apparently affect insects across several orders, and also affects other arthropods (some species of arachnids) (Zimmermann 2008). Other studies cited by the registrant in the rationale (but not included for review by BPPD) indicate that some avoidance behaviors exhibited by predatory insects may reduce their potential for infection by consumption of infected prey, and that synergistic effects on the pest population reductions have been observed as a result of the presence of the *P. fumosoroseus* and the predatory insect. These indicate that some species are not susceptible to *P. fumosoroseus*.

There are some uncertainties surrounding the use of these studies for predicting effects on insects in the field. One issue related to the studies presented from the literature is that they all present results from different strains of *P. fumosoroseus*. Effects on any particular nontarget species may be strain specific, and some strains may be more virulent toward certain species than others. Additionally, Zimmermann (2008) describes *P. fumosoroseus* (*I. fumosorosea*) as polymorphic and a species aggregate or complex. Therefore, while these studies may show effects or lack thereof, the extent to which their results represent the potential of those of *P. fumosoroseus* Apopka Strain 97 are unknown.

The point was also made in the rationale, as well as several of the papers cited, that laboratory conditions, especially high relative humidity, may promote infection and are not necessarily representative of the more complex field environment. This is a common factor related to all types of laboratory toxicity and/or pathogenicity testing. However, the following points must also be considered:

- Laboratory conditions would thus represent the worst-case scenario and, therefore, the most conservative representation of the potential for effects
- High humidity can occur in the field, and is common in some regions of the U.S. during some seasons
- The authors of these studies also note that effects may be greater in insects that are “stressed.” The “stress” was not described, but laboratory conditions may offer a reduced-stress environment, since food is usually in plentiful supply, the risk of predation is reduced, and environmental conditions do not fluctuate widely as they do in the field. Stressful conditions in the field would include extreme low humidity and high temperatures of other physiologically strenuous conditions, which may result in greater vulnerability to infection.

Conditions in the field would be expected to fluctuate. Some conditions may be more favorable for infection than others, but these cannot be predicted. Since *P. fumosoroseus* Apopka strain 97 is expected to have some efficacy in the field on the target insects, it is expected that conditions favoring infection of other susceptible species would occur.

According to the proposed label, the pest species controlled by *P. fumosoroseus* Apopka strain 97 span several insect orders (Hemiptera, Thysanoptera, Diptera, Lepidoptera, and Coleoptera), and also include symphylans (Class Symphyla, Order Symphyla), mites (Class Arachnida, Order Acari), and “other soil insects.” This is a wide range of arthropods to which *P. fumosoroseus* Apopka strain 97 is assumed to be pathogenic. Without extensive testing or a clear understanding of species-related factors influencing infectivity and pathogenicity of this strain of *P. fumosoroseus*, it is not reasonable to assume that effects would only occur to pest species in these classes/orders and not beneficial (or otherwise neutral) species. The review by Zimmermann (2008) also includes insects from Orders Blattodea, Hymenoptera, Isoptera, and Neuroptera, as well as tick species in the arachnid Order Acari. The neuropteran species listed include *Crysoperla carnea* (green lacewing), which is a beneficial species. The USDA-ARSEF ARS Collection of Entomopathogenic Cultures report for *Isaria* spp. (Humber et al. 2011), lists insects from Orders Lepidoptera, Diptera, Coleoptera, Hemiptera, Homoptera, Hymenoptera, as well as tick species (some of these reports were included in Zimmermann 2008).

Based on the available information, *Paecilomyces fumosoroseus* Apopka Strain 97 could potentially result in adverse effects in several species of insects and other terrestrial arthropods. While not all species may be affected, the information provided is not sufficient to be able to predict which species may or may not be affected by this particular strain with field applications. *P. fumosoroseus* is known to be pathogenic to a wide range of insects and some arachnids, and the extent to which the Apopka strain 97 is pathogenic to these arthropods cannot be known without extensive testing. Therefore, BPPD concludes that *P. fumosoroseus* Apopka strain 97 is likely to cause adverse effects in nontarget insects as a result of the proposed new uses.

Honey Bees

As with other nontarget insects, honey bees are also expected to receive exposure to *Paecilomyces fumosoroseus* Apopka Strain 97 as a result of the proposed new labeled uses. A study was conducted to determine the toxicity of *Paecilomyces fumosoroseus* Apopka Strain 97 to honey bees (MRID 47939509). In this study, the oral LD₅₀ was determined to be >21.63 µg a.i./bee (calculated intake), and the contact LD₅₀ was >20.0 µg a.i./bee. The study was sufficient to show that *Paecilomyces fumosoroseus* Apopka strain 97 is not toxic to honey bees, but it was not of sufficient duration to determine pathogenicity.

Additional rationale was submitted to supplement this study (MRID 48357704). Several pieces of information were presented to show that *Paecilomyces fumosoroseus* Apopka strain 97 may be unlikely to cause adverse effects on honey bees. Much research has focused on the microflora of honey bees and their hives, and *Paecilomyces fumosoroseus* is not widely reported as a pathogen of honey bees. Additionally, honey bees exhibit individual and communal cleansing behaviors that would be expected to reduce exposure, though solitary bees or other species that do not have these behaviors might have higher exposure. Goettel et al. (1990) list honey bees and bumblebees among the many insect species from which *Paecilomyces farinosus* had reportedly been isolated without apparent effects; however these authors also caution against direct exposure of bees to treatments containing entomopathogens.

The USDA-ARS ARSEF Collection of Entomopathogenic Cultures (ARSEF) annual report does not contain references to isolations of *Paecilomyces fumosoroseus* (or *Isaria fumosorosea*) from bees, but does include isolations from other hymenopterans (ants and parasitoid wasps) (Humber et al. 2011). While this may indicate that bees are not hosts of this fungus, a caution with reliance on this reference is that the situations in which isolates are provided may vary, and isolations will only be included where there is an interest or need to submit samples for identification. Some instances of pathogenicity in bees may be missed in this case; however, given the recent interest in understanding causes of honey bee mortality, the likelihood is greater that attention will be given to discoveries of bee pathogens.

In the rationale submitted, the registrant states that reports of *Beauveria bassiana* pathogenicity to bees is absent from reviews of the literature, but ARSEF contains several reports of *B. bassiana* associated with bees. Therefore, the extent to which lack of reports in the literature can be used as justification for lack of effects is dependent on the extent to which these effects are investigated as well as the literature surveyed. An additional literature search was performed by BPPD. The Environmental Information Search literature database was searched, for all years available (1926 – present) with the terms “*Paecilomyces*” or “*Isaria*” and “bee.” This database simultaneously searches the Agricola; Biosis Previews; CAB Abstracts; Energy, Science, and Technology, General Science Abstracts, and the National Technical Information Service literature databases. The ISI Web of Knowledge literature database was also searched with these terms for all years available in the database. Several reports were found for exposure of *Paecilomyces* spp. to various species of bees, in some cases through treatments intentionally applied to hives for control of varroa mites (*Varroa destructor*). No reports of adverse effects to bees were found in any of these searches, though it was not clear whether the effects on bees were the focus of study in all cases.

Based on the information presented as well as an additional search of the available literature, adverse effects to honey bees are unlikely as a result of acute toxicity. There is no evidence that *P. fumosoroseus* Apopka strain 97 is likely to be pathogenic to bees; however there is uncertainty due to the fact that this has not been adequately tested and because *P. fumosoroseus* can affect a wide range of insects and other arthropods. Therefore, BPPD concludes that pathogenicity of *Paecilomyces fumosoroseus* Apopka strain 97 to honey bees is still a concern at the proposed field application rates. Goettel et al. (1990) also noted that while some of the *Paecilomyces* spp. may not be pathogenic where they naturally occur, direct spray is not recommended. Therefore, it is recommended that the label contain language prohibiting application of *Paecilomyces fumosoroseus* Apopka strain 97 when bees are present.

Other Terrestrial Nontarget Organisms

The risk assessment conducted for the initial registration of *Paecilomyces fumosoroseus* Apopka Strain 97 indicated reports of *Paecilomyces fumosoroseus* infections in other nontarget organisms (e.g., a captive giant tortoise, Georg et al. 1962). Most reports were of secondary infections in immunocompromised or otherwise physiologically stressed individuals, and information from the literature on the potential for beauverolides to exhibit strong immunomodulating activity was noted (BPPD 1996). In the case of the giant tortoise described above, *Paecilomyces fumosoroseus* was isolated from one captive tortoise after the normal temperature in its pen had been accidentally lowered. Koch's postulates were not fulfilled with *Paecilomyces fumosoroseus* to demonstrate that this fungus was the cause of the disease, but the authors concluded that while *P. fumosoroseus* appeared to cause the pulmonary disease, they did not know whether it was the cause of the tortoise's death. They also stated that it was clear that the body's tissues were reacting well to destroy the disease, and that *Paecilomyces fumosoroseus* may have been capable of infecting the tortoise because the lowered ambient temperature had reduced the normal threshold of resistance for the tortoise. BPPD previously determined that the infection may also have been facilitated by the production of beauverolides. As discussed above, as long as beauverolides are not present in significant quantities in the EP, there will be no concern for potential immunomodulating effects of these mycotoxins to other nontarget organisms.

BPPD also noted (USEPA 1998) that no effects were observed in frogs exposed to a single oral dose of *Paecilomyces fumosoroseus*. While the above incident indicates the possibility that *Paecilomyces fumosoroseus* may infect cold-blooded terrestrial animals, it represents one isolated case in unnatural conditions. An additional literature search was conducted to find any other reports of *Paecilomyces fumosoroseus* infections in reptiles and amphibians. The same databases were used as described above, and the search terms "*Paecilomyces*" or "*Isaria*" were used with "reptile," "tortoise," "amphibian," and "frog." No additional reports of associations between this fungus and reptiles or amphibians were found. At this time, BPPD does not have additional concerns for these nontarget organisms; however, reports of confirmed infections in these animals from the literature or elsewhere will trigger the need for additional testing.

Nontarget Plants

Nontarget plants on the field and in areas contacted by spray drift would be exposed to *Paecilomyces fumosoroseus* Apopka strain 97. The previous assessment for *Paecilomyces fumosoroseus* Apopka Strain 97 mentioned limited reports of pathogenicity to plants. The USDA-ARS Fungal Database (<http://nt.ars-grin.gov/fungaldatabases/index.cfm>) indicates 26 host-fungus combinations. Several of these are insects, and reports related to plants do not appear to be indicative of pathogenic relationships. A search of the literature using the data bases above and the search terms “*Paecilomyces fumosoroseus*” and “plant pathogen” did not produce reports of plant pathogenicity resulting from *Paecilomyces fumosoroseus* infection. *Paecilomyces fumosoroseus* is not otherwise known to be taxonomically related to any plant pathogen, and nontarget plant testing was not required. *P. fumosoroseus* is commonly also found in soils worldwide, and it is reasonable to expect that plants are naturally exposed to this fungus. Additionally, *P. fumosoroseus* has been used in biocontrol programs for control of plant insect pests, and adverse effects on plants have not been reported. Based on this information, adverse effects of *P. fumosoroseus* Apopka strain 97 to nontarget plants are not expected as a result of the proposed new labeled uses.

2. Aquatic Animals and Plants

Freshwater Fish and Invertebrates

Certis presented rationale (MRID 47939506) to support the conclusion that exposure in aquatic environments would not be significant. Their rationale included studies that showed that *Paecilomyces fumosoroseus* Apopka strain 97 is not expected to be toxic to freshwater fish or invertebrates. Additional testing to determine pathogenicity was not performed, but Certis submitted rationale stating that the proposed applications to outdoor crops would not result in measurable elevated levels due to runoff. However, they did not address the potential for drift. The influence of drift is important, since aerial applications are allowed on the proposed label.

Since applications can be made as sprays with both ground and aerial equipment, a spray drift analysis was performed using the AgDRIFT® program. For an aerial assessment, a fine to medium spray droplet size was assumed to adequately represent a low-volume application. An aerial application made directly to a body of water 15 cm deep (consistent with the EPA standard wetland) at the maximum rate of 2 lbs PFR-97 per acre (at 1.9×10^9 cfu/g) would result in a concentration of 2,842 cfu/mL. Spray drift from an aerial spray to the same body of water adjacent to the treated area would deposit 12.7% of the applied amount into it, resulting in a concentration of approximately 360 cfu/mL. The resulting concentration to an adjacent pond of 2 m depth (consistent with the EPA standard pond) would be approximately 25 cfu/mL. Assuming very fine to fine droplet size for a ground application would result in approximately 6.2% of the applied amount reaching the water body, which would give a concentration of 170 cfu/mL to an adjacent wetland or approximately 13 cfu/mL to a pond. BPPD agrees that in most cases the resulting concentration of *Paecilomyces fumosoroseus* Apopka Strain 97 in adjacent water bodies will not be significantly elevated, but aerial applications may result in elevated concentrations in relatively shallow waters (e.g., wetlands). The label suggests reapplication every 3-10 days, and depending on environmental conditions and the viability of the active

ingredient in water, reapplication may result in higher concentrations. Therefore, the waiver rationale submitted does not necessarily support all aerial applications of *Paecilomyces fumosoroseus* Apopka strain 97.

Paecilomyces fumosoroseus Apopka Strain 97 has been tested on embryos of *Myosoidopsis bahia* and *Penaeus duorarum* and was not found to be toxic or pathogenic to these aquatic (estuarine) invertebrates (USEPA 1997). A search of the literature (using the same databases as described above) also did not return any reports of pathogenicity of *Paecilomyces fumosoroseus* in fish or aquatic invertebrates. Additionally, studies by EPA's Gulf Breeze Ecology Lab indicate that pathogenic effects of other entomopathogens (*Beauveria bassiana* and *Metarhizium anisopliae*) on fish embryos are seen at concentrations of $\geq 10^4$ cfu/mL (Genthner and Middaugh 1992, 1995). Therefore, BPPD does not expect pathogenicity to fish at the concentrations determined above. However, confirmatory data should be submitted to show that elevated concentrations resulting from aerial applications due to drift will not result in pathogenicity to freshwater fish and invertebrates. These data may include pathogenicity testing on freshwater fish and invertebrates, or may include, for example, additional information on viability or natural concentrations in water or other scientifically supported rationale.

Marine/Estuarine Fish and Invertebrates

Based on the expected concentrations calculated above for freshwater environments, exposure in marine and estuarine environments is expected to be low as a result of dilution. As noted above, *Paecilomyces fumosoroseus* Apopka Strain 97 was not found to be toxic or pathogenic to two species of estuarine shrimp. Therefore, *Paecilomyces fumosoroseus* Apopka Strain 97 is not expected to reach these environments in significant quantities, and adverse effects to marine/estuarine fish and invertebrates are not expected as a result of the proposed new uses.

Aquatic Plants

P. fumosoroseus is commonly found in soils worldwide, and it is reasonable to expect that aquatic plants are naturally exposed to this fungus via runoff. *Paecilomyces fumosoroseus* is not taxonomically related to any known plant pathogen, so nontarget testing with aquatic plants was not required. BPPD does not anticipate adverse effects to aquatic plants as a result of the proposed new uses.

D. Threatened and Endangered Species Assessment

As indicated in the analysis above, EPA has determined that adverse effects to nontarget insects as a result of the proposed new uses of *Paecilomyces fumosoroseus* Apopka strain 97 are likely. EPA has determined that risk of adverse effects is minimal to birds, wild mammals, freshwater fish and invertebrates, estuarine/marine fish and invertebrates, and nontarget terrestrial and aquatic plants. Therefore, EPA makes conclusions as follows regarding federally threatened and endangered (listed) species for the proposed new uses of *Paecilomyces fumosoroseus* Apopka 97.

- EPA makes “No Effect” determinations for direct effects to listed terrestrial vertebrates and plants and listed aquatic animals and plants for the proposed new uses.
- EPA concludes that the proposed new uses of *Paecilomyces fumosoroseus* Apopka 97 have the potential to cause direct effects to listed terrestrial insects and arachnids, as well as indirect effects to listed species dependent on insects and arachnids (e.g., for food, pollination, habitat maintenance). Further analyses are needed to characterize the effects that are likely to occur and the species potentially affected. Tier II environmental expression studies would allow for a more refined analysis and would likely reduce the number of species determined to be affected.

II. Environmental Assessment Summary

The Agency has performed an environmental risk assessment based on the data, literature citations, and data waiver rationale provided by the registrant for *Paecilomyces fumosoroseus* Apopka Strain 97. *Paecilomyces fumosoroseus* (recently reclassified into *Isaria fumosorosea*) is an entomopathogen that is known to have a relatively wide host range. It is widely distributed, has been isolated from many species of insects, particularly Lepidoptera, and has been collected from air, water, plants, other fungi, and often from soil. It is one of the most common entomopathogens known to affect nymphs and adults of *Bemisia* spp. of whiteflies, and has caused epizootics in this species in the U.S. and other countries (Zimmermann 2008).

The proposed expanded uses of *Paecilomyces fumosoroseus* Apopka Strain 97 pose an increased potential for exposure to nontarget organisms, and the registrant that the proposed new uses of *Paecilomyces fumosoroseus* Apopka Strain 97 pose risk to nontarget insects and other sensitive arthropods (e.g., arachnids), but not to other terrestrial or aquatic animals or plants. A “No Effect” determination is made for direct effects to federally listed threatened and endangered (“listed”) terrestrial vertebrates and plants and listed aquatic animals and plants for the proposed new uses. However, these uses have the potential to result in direct effects to listed insects and arachnids as well as indirect effects to listed species dependent on insects and arachnids (e.g., for food, pollination, habitat maintenance). Further analyses are needed to characterize the effects that are likely to occur and the species potentially affected. Tier II environmental expression studies would allow for a more refined analysis and would likely reduce the number of species determined to be affected.

References Cited

- Biopesticides and Pollution Prevention Division (BPPD). 1996. Memorandum from G. Tomimatsu (OPP/BPPD) to S. Bacchus (OPP/BPPD), Re: Microbial Pesticide Review, *Paecilomyces fumosoroseus* Apopka Strain 97. Dated October 8, 1996.
- Genthner, F. J. and D. P. Middaugh. 1992. Effects of *Beauveria bassiana* on the embryos of the inland silverside fish (*Menidia beryllina*). *Applied and Environmental Microbiology* 58: 2840-2845.

- Genthner, F. J. and D. P. Middaugh. 1995. Nontarget testing of an insect control fungus: effects of *Metarhizium anisopliae* on developing embryos of the inland silverside fish *Menidia beryllina*. *Diseases of Aquatic Organisms* 22: 163-171.
- Georg, L.K., W. M. Williamson, E. B. Tilden, and R. E. Getty. 1962. Mycotic pulmonary disease of captive giant tortoise due to *Beauveria bassiana* and *Paecilomyces fumosoroseus*. *Sabouraudia* 2:80-86.
- Goettel, M. S., T. J. Poprawski, J. D. Vandenburg, Z. Li, and D. W. Roberts. 1990. Safety to nontarget invertebrates of fungal biocontrol agents. Pp. 209-231 *In*: M. Laird, L. A. Lacey, and E. W. Davidson, eds. *Safety of Microbial Insecticides*. CRC Press, Boca Raton.
- Humber, R. A., K. S. Hansen, and M. M. Wheeler. 2011. ARSEF ARS Collection of Entomopathogenic Fungal Cultures: *Isaria* plus *Paecilomyces* and *Evalchovea*. January 24, 2011. USDA-ARS, Ithaca, NY. 50 pp. Accessed at: <http://www.ars.usda.gov/SP2UserFiles/Place/19070510/Isaria%20Jan2011.pdf>.
- U.S. Environmental Protection Agency (USEPA). 1998. Registration Eligibility Document: *Paecilomyces fumosoroseus* Apopka Strain 97 (PC Code 115002). Office of Pesticide Programs, Biopesticides and Pollution Prevention Division.
- USEPA. 1997. Internal Report: Estuarine invertebrate testing of the entomopathogenic fungus, *Paecilomyces fumosoroseus* Apopka Strain 97. Office of Research and Development, Gulf Ecology Division, National Health and Environmental Effects Research Laboratory, Gulf Breeze, Florida.
- Zimmermann, G. 2008. The entomopathogenic fungi *Isaria farinosa* (formerly *Paecilomyces farinosus*) and the *Isaria fumosorosea* species complex (formerly *Paecilomyces fumosoroseus*): biology, ecology and use in biological control. *Biocontrol Science and Technology* 18: 865-901.